K002767

SEP 27 2000

510(k) Summary

Herbert J. Semler
1 September 2000

Trade name - CompressAR® 3 Finger Jack™ Disc and StrongArm™ System
Common name - femoral access compression device
Classification name - Clamp, Vascular

This device is similar to the CompressAR® Universal System CompressAR® Comfort™ Disc, and is a modification of this predicate device. The CompressAR® 3 Finger Jack™ Disc provides a flexible compression pad, with a shape representative of fingers, and is used with the modified arm and attachment to provide a pivoting connection.

The CompressAR® 3 Finger Jack™ Disc and StrongArm™ System is intended for use during and following femoral vascular catheterization procedures to assist in obtaining and maintaining hemostasis.

The disk and supporting stand provide a mechanical means of holding external pressure at or near the site of femoral vascular access. Direct pressure is used to obtain and maintain hemostasis, in a similar fashion to direct hand pressure on the access site or at a pressure point.

Testing was conducted to determine that the modified device provides mechanical clamping and holding functions, similar to the predicate device. It was concluded that the CompressAR® 3 Finger Jack™ Disc and StrongArm™ System is equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2000

Herbert J. Semler, M.D.
Official Correspondent
Semler Technologies, Inc.
501 S.E. Columbia Shores Blvd., Suite 100
Vancouver, WA 98661-8064

Re: K002767
Trade Name: CompressAR® Femoral Access Compression Device
Regulatory Class: II (two)
Product Code: 74 DXC
Dated: September 5, 2000
Received: September 6, 2000

Dear Dr. Semler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: CompressAR® Femoral Access Compression Device

Indications For Use:

This device is indicated for use to provide hemostasis of the femoral vascular access site during and following catheterization or cannulation procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER ~~PAGE IF~~ NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002747

(Optional Format 3-10-98)